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Attorneys for Defendants Lupin Limited and Lupin Pharmaceuticals, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BAYER SCHERING PHARMA AG & BAYER HEALTHCARE PHARMACEUTICALS INC., Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Case No. 2:10-cv-5423-PGG

ANSWER AND COUNTERCLAIM

Defendants Lupin Pharmaceuticals, Inc. ("LPI") and Lupin Limited (collectively, "Lupin") by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by Plaintiffs Bayer Schering Pharma AG & Bayer HealthCare Pharmaceuticals Inc. ("Plaintiffs") as follows:

PARTIES

1. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and, therefore, denies them.

2. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and, therefore, denies them.

3. Lupin admits that Lupin Limited is a company organized and existing under the laws of India, has a place of business at Laxmi Towers "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India, and has a registered office at 159 C.S.T. Road, Kalina, Santacruz (East), Mumbai 400 098, India. Lupin further admits that Lupin Limited manufactures and sells pharmaceutical products through subsidiaries, including through LPI, but denies the remaining allegations in paragraph 3 of the Complaint.

4. Lupin admits that LPI is a corporation organized and existing under the laws of the State of Virginia, and has a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin further admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies the remaining allegations in paragraph 4 of the Complaint.

5. Lupin admits that Lupin Limited submitted ANDA No. 20-1663 to the U.S. Food and Drug Administration ("FDA") which seeks FDA approval to market the drospirenone and ethinyl estradiol product described in ANDA No. 20-1663 ("Lupin Limited's drospirenone and

ethinyl estradiol tablets") in the United States. Lupin further admits that LPI or a designee plans to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States as soon as permitted to do so by any applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 5 of the Complaint.

6. Lupin admits that LPI is designated as Lupin Limited's U.S. agent in connection with Lupin Limited's ANDA No. 20-1663 which seeks FDA approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States. Lupin denies the remaining allegations in paragraph 6 of the Complaint.

JURISDICTION AND VENUE

7. For the purposes of this action only, Lupin does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). The remaining assertions in Paragraph 7 comprise legal conclusions to which no answer is required. To the extent an answer to any factual answer not otherwise addressed herein is required, Lupin denies said allegation

8. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. The remaining assertions in paragraph 8 comprise legal conclusions to which no answer is required. To the extent an answer to any factual allegation not otherwise addressed herein is required, Lupin denies said allegation.

9. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin is

without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 9 of the Complaint and, therefore, denies them.

10. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, which includes the State of New York, and that residents of the State of New York may purchase drug products offered for sale by LPI. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10 of the Complaint and, therefore, denies them.

11. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, and that residents of the State of New York may purchase drug products offered for sale by LPI. Lupin denies any remaining allegations in paragraph 11 of the Complaint.

12. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, which market includes the State of New York, and derives revenue from those sales. Lupin denies any remaining allegations in paragraph 12 of the Complaint.

13. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 13 of the Complaint.

14. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 14 of the Complaint.

15. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 15 of the Complaint.

16. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 16 of the Complaint.

17. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI or a designee plans to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States as soon as permitted to do so by the applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 17 of the Complaint.

18. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, which market includes the State of New York. The remaining assertions in Paragraph 18 comprise legal conclusions to which no answer is required. To the extent an answer to any factual allegation not otherwise addressed herein is required, Lupin denies said allegation.

19. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 of the Complaint and, therefore, denies them.

20. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, which market includes the State of New York, and that residents of the State of New York may purchase drug products offered for sale by LPI. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 20 of the Complaint and, therefore, denies them.

21. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market, and that residents of the State of New York may purchase drug products offered for sale by LPI. Lupin denies any remaining allegations in paragraph 21 of the Complaint.

22. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market and derives revenue from those sales, which market includes the State of New York. Lupin denies any remaining allegations in paragraph 22 of the Complaint.

23. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 23 of the Complaint.

24. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 24 of the Complaint.

25. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 25 of the Complaint.

26. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies any remaining allegations in paragraph 26 of the Complaint.

27. Lupin admits that or a designee plans to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States as soon as permitted to do so by the applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 27 of the Complaint.

28. For purposes of this action only, Lupin does not contest venue in this judicial district.

BACKGROUND

29. Lupin admits that the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") lists "Bayer Hlthcare" as the applicant in connection with Application No. 21-098 (Proprietary Name: Yasmin®), with the dosage form and active ingredient thereof being described in the Orange Book as "tablet" and "drospirenone, ethinyl estradiol," respectively. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 29 of the Complaint and, therefore, denies them.

30. Lupin admits that the dosage strengths listed in the Orange Book for Yasmin® are 3 mg and 0.03 mg for drospirenone and ethinyl estradiol, respectively. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 30 of the Complaint and, therefore, denies them.

31. Lupin admits that Lupin Limited submitted ANDA No. 20-1663 to the FDA which seeks approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets described therein in the United States. Lupin denies the remaining allegations in paragraph 31 of the Complaint.

32. Lupin admits that each of Lupin Limited's drospirenone and ethinyl estradiol tablets contain, *inter alia*, 3.0 mg of drospirenone and 0.03 mg ethinyl estradiol. Lupin denies the remaining allegations in paragraph 32 of the Complaint.

33. Lupin admits that on June 2, 2010, Lupin Limited sent letters to Bayer HealthCare Pharmaceuticals, Inc. and Bayer Schering Pharma Aktiengesellschaft pursuant to and in compliance with 21 U.S.C. § 355(j)(2)(B)(ii), informing them that Lupin Limited submitted ANDA No. 20-1663 to the FDA, and that the ANDA contains a Paragraph IV Certification with

respect to U.S. Patent Nos.: 5,569,652; 6,787,531; and 6,933,395, this certification asserting that these three patents are invalid and/or will not be infringed by Lupin Limited's drospirenone and ethinyl estradiol tablets. Lupin denies the remaining allegations in paragraph 33 of the Complaint.

PATENTS-IN-SUIT

34. Lupin admits that the Complaint alleges two counts of patent infringement of U.S. Patent No. 5,569,652.

35. Lupin admits that U.S. Patent No. 5,569,652 ("the '652 patent") identifies, on its first page, an issue date of October 29, 1996. Lupin further admits that the '652 patent lists Sybille Beier, Walter Elger, Yukishige Nishino, and Rudolf Wiechert as inventors, and that the '652 patent lists a filing date of December 7, 1993. Lupin also admits that a copy of the '652 patent is attached as Exhibit 1 to the Complaint. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 35 of the Complaint and, therefore, denies them.

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF U.S. PATENT NO. 5,569,652 UNDER § 271(E)(2)(A)

36. Lupin incorporates by reference its responses to paragraphs 1 to 35 of the Complaint as if fully set forth herein.

37. Lupin admits that Lupin Limited submitted ANDA No. 20-1663 to the FDA which seeks approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets in the United States. Lupin further admits that LPI or a designee plans to market the drospirenone and ethinyl estradiol product described in ANDA No. 20-1663 in the United States as soon as permitted to do so by any applicable statutes and regulations. Lupin denies that Lupin Limited's drospirenone and ethinyl estradiol tablets infringe any valid and enforceable claim of the '652

patent. The remainder of paragraph 37 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in the remaining allegations of paragraph 37 of the Complaint, Lupin denies them.

38. Lupin admits that the Orange Book associates the '652 patent with Yasmin®. The remaining allegations in paragraph 38 of the Complaint state legal conclusions to which no answer is required. To the extent any factual assertions are included in the remaining allegations in paragraph 38 of the Complaint, Lupin denies them.

39. Paragraph 39 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 39 of the Complaint, Lupin denies them.

40. Lupin admits that Lupin Limited submitted ANDA No. 20-1663 to the FDA which seeks approval to market Lupin's drospirenone and ethinyl estradiol tablets in the United States, which tablets are bioequivalent to Yasmin®. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 40 of the Complaint and, therefore, denies them.

41. Paragraph 41 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 41 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 41 of the Complaint and, therefore, denies them.

42. Paragraph 42 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 42 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 42 of the Complaint and, therefore, denies them.

43. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 43 of the Complaint and, therefore, denies them.

44. Lupin admits that the Lupin Limited website identifies certain products manufactured by Lupin Limited, and that Lupin Limited products are marketed where approved by relevant regulatory authorities. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 44 of the Complaint and, therefore, denies them.

45. Lupin admits that Lupin Limited products are marketed where approved by relevant regulatory authorities. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 45 of the Complaint and, therefore, denies them.

46. Lupin admits that Lupin Limited submitted ANDA No. 20-1663 to the FDA seeking approval to market Lupin's drospirenone and ethinyl estradiol tablets in the United States. Lupin further admits that LPI or a designee plans to market the drospirenone and ethinyl estradiol product described in ANDA No. 20-1663 in the United States as soon as permitted to do so by any applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 46 of the Complaint.

47. Paragraph 47 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 47 of the Complaint, Lupin denies them.

COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF U.S. PATENT NO. 5,569,652 UNDER § 271(B)

48. Lupin incorporates by reference its responses to paragraphs 1 to 47 of the Complaint as if fully set forth herein.

49. Lupin admits that Lupin Limited submitted ANDA No. 20-1663 to the FDA seeking approval to market Lupin's drospirenone and ethinyl estradiol tablets in the United States. Lupin further admits that LPI or a designee plans to market the drospirenone and ethinyl estradiol product described in ANDA No. 20-1663 in the United States as soon as permitted to do so by any applicable statutes and regulations. The remaining allegations in paragraph 49 state legal conclusions to which no answer is required. To the extent any factual assertions are included in the remaining allegations in paragraph 49 of the Complaint, Lupin denies them.

50. Paragraph 50 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 50 of the Complaint, Lupin denies them.

PRAYER FOR RELIEF

Lupin denies that plaintiffs are entitled to the judgment and relief requested in the Prayer for Relief set forth in the Complaint.

AFFIRMATIVE AND SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 50 of the Complaint, Lupin alleges the following Affirmative and Separate Defenses to the Complaint.

First Defense
(Invalidity of the '652 patent)

51. The '652 patent, and each of the claims 1 through 27 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

Second Defense
(Noninfringement of the '652 Patent)

52. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '652 patent.

Third Defense
(Limitation of Remedies)

53. The remedy of an injunction or other equitable relief sought by Plaintiffs in its Complaint is unavailable to Plaintiffs in this action.

COUNTERCLAIMS

54. Defendant/Counterclaim-Plaintiff Lupin Limited brings the following Counterclaims against Plaintiff/Counterclaim-Defendants Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") for a declaratory judgment that U.S. Patent Nos. 5,569,652 and 6,933,395 are invalid and not infringed by Lupin Limited's drospirenone and ethinyl estradiol tablets that are the subject of ANDA No. 20-1663.

THE PARTIES

55. Counterclaim-Plaintiff Lupin Limited is corporation organized and existing under the laws of India having a place of business at Laxmi Towers "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India, and has a registered office at 159 C.S.T. Road, Kalina, Santacruz (East), Mumbai 400 098, India.

56. Upon information and belief, Counterclaim-Defendant Bayer Schering Pharma AG is a corporation organized under the laws of the Federal Republic of Germany, having its principal place of business in Müllerstrasse 178, 13353 Berlin, Germany.

57. Upon information and belief, Counterclaim-Defendant Bayer HealthCare Pharmaceuticals Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 6 West Belt, Wayne, New Jersey 07470.

BACKGROUND

58. Lupin Limited filed ANDA No. 20-1663 with the FDA seeking approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets, referencing the approved

NDA for Yasmin®. The ANDA provides data showing that Lupin Limited's drospirenone and ethinyl estradiol tablets are bioequivalent to Yasmin®, which is the subject of Bayer's NDA No. 21-098.

59. U.S. Patent Nos. 5,569,652 ("the '652 patent"), 6,787,531 ("the '531 patent"), and 6,933,395 ("the '395 patent") in the Orange Book in connection with NDA No. 21-098 for Yasmin®. Upon information and belief, Bayer listed those patents, and in doing so contends that the claims of these patents describe and cover the drug Yasmin®, or a method of using that drug, and that a suit for infringement could reasonably be brought against any generic manufacturer that attempts to seek approval to market a generic version of Yasmin® before any of the aforementioned patents expire. *See* 21 U.S.C. § 355(b)(1)-(c)(2).

60. In 2008, the '531 patent was held invalid due to obviousness in *Bayer Schering Pharma AG v. Barr Labs., Inc.*, Civil Action No. 05-cv-2308, 2008 WL 628592 (D.N.J. Mar. 3, 2008). This decision was later affirmed by the Federal Circuit. *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341 (Fed. Cir. 2009).

61. Because Lupin Limited seeks FDA approval to market Lupin Limited's drospirenone and ethinyl estradiol tablets before the expiration of each of the '652, '531, and '395 patents, Lupin Limited's ANDA No. 20-1663 includes a paragraph IV certification for each of the aforementioned patents.

62. On or about June 2, 2010, Lupin Limited provided Bayer the statutorily-mandated notice letter of its paragraph IV certification on each of these patents. This notice letter met the statutory requirement for such notice letters, and included a detailed statement of the factual and legal bases for its opinion that, *inter alia*, the '652, '531, and '395 patents are invalid and/or not infringed by Lupin Limited's drospirenone and ethinyl estradiol tablets. The submission to the

FDA of an ANDA containing a paragraph IV certification constitutes a technical act of infringement.

JURISDICTION AND VENUE

63. Lupin Limited re-alleges and incorporates by reference the allegations of paragraphs 54-62.

64. Plaintiffs have brought an action against Lupin Limited for allegedly infringing the '652 patent. There exists an actual case or controversy between Lupin Limited and Plaintiffs as to Lupin Limited's alleged infringement of the '652 patent.

65. There further exists an actual case or controversy between Lupin Limited and Plaintiffs as to the '395 patent based on Bayer's listing of this patent in the Orange Book in connection with NDA No. 21-098 for Yasmin®.

66. This Court has subject matter jurisdiction over a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a) and 1367, based on an actual controversy between Lupin Limited and Counterclaim Defendants Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

67. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b). Venue also is proper as a result of the filing of the present action by Plaintiffs against Lupin Limited in this judicial district.

LUPIN LIMITED IS ENTITLED TO DECLARATORY JUDGMENT

68. On July 15, 2010, Bayer filed the present lawsuit in this Court against Lupin Limited and Lupin Pharmaceuticals, Inc. alleging patent infringement of the '652 patent only by Lupin Limited's filing of ANDA No. 20-1663 for a generic version of Yasmin®.

69. Bayer did not bring a lawsuit alleging infringement of the '395 patent by Lupin Limited's filing of ANDA No. 20-1663 for a generic version of Yasmin®. But by listing this patent in the Orange Book in connection with NDA No. 21-098 for Yasmin®, Bayer maintains that the claims of this patent describe and cover Yasmin®, or a method of using Yasmin®, and that a suit for infringement could reasonably be brought against any ANDA applicant that attempts to seek approval to market a generic version of Yasmin® before the aforementioned patent expires. *See* 21 U.S.C. § 355(b)(1)-(c)(2). Bayer's listing of the '395 patent in the Orange Book in connection with NDA No. 21-098 creates the requisite justiciable case or controversy and subject matter jurisdiction for a generic manufacturer that makes a paragraph IV certification on these patents to bring a declaratory judgment action.

70. A generic manufacturer, like Lupin Limited, that has submitted an ANDA containing a paragraph IV certification on a patent is entitled to bring and maintain a declaratory judgment action against the NDA holder/patent holder on that patent if the following have occurred: (1) 45 days have elapsed since the paragraph IV certification was received by the NDA holder/patent holder; (2) neither the NDA holder nor the patent holder has filed a suit for patent infringement on the patent subject to the paragraph IV certification within the 45-day period; and (3) an offer of confidential access to the ANDA is included in the notice of paragraph IV certification provided to the NDA holder/patent holder. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

71. Because Lupin Limited has provided the offer to confidential access to its ANDA pursuant to 21 U.S.C. § 355(i)(5)(C)(i)(III), and Bayer did not sue Lupin Limited on the '395 patent within 45 days of receiving Lupin Limited's notice of paragraph IV certification, Lupin

Limited is statutorily permitted to bring and maintain a declaratory judgment action against Bayer pursuant to 21 U.S.C. § 355(j)(5)(C).

72. Lupin Limited further requires a court decision of non-infringement and/or invalidity on the ’395 patent to prevent it from risking infringement liability on this patent if (and when) it begins marketing its generic version of Yasmin® before this patent expires. This harm can be alleviated through a declaration of patent certainty on non-infringement and/or invalidity from this Court on the ’395 patent.

73. On April 18, 2007, Bayer filed a lawsuit in this Court against Sandoz, Inc. (“Sandoz”), Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. (collectively, “Watson”) alleging infringement of the ’652 patent by Sandoz’ and Watson’s respective filings of ANDAs for a generic version of Yasmin®.

74. On September 26, 2008, Bayer filed a Statement of Non-Liability as to Defendant Sandoz and U.S. Patent No. 6,933,395, which stated that Sandoz had no liability to Plaintiffs or any successors-in-interest to the ’395 patent for infringement of any of the claims of the ’395 patent in connection with Sandoz’ ANDA and that Bayer Schering would not sue Sandoz for infringement of any of the claims of the ’395 patent in connection with Sandoz’ ANDA product.

First Count
(Declaration of Invalidity of the ’652 Patent)

75. Lupin Limited incorporates the allegations set forth in paragraphs 54 through 74 of the Counterclaims as if fully set forth herein.

76. The ’652 patent, including claims 1 through 27 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

77. There is an actual case or controversy as to the invalidity of claims 1 through 27 of the ’652 patent.

Second Count
(Declaration of Noninfringement of the '652 Patent)

78. Lupin Limited incorporates the allegations set forth in paragraphs 54 through 74 of the Counterclaims as if fully set forth herein.

79. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '652 patent.

80. There is an actual case or controversy as to the infringement of claims 1 through 27 of the '652 patent.

Third Count
(Declaration of Invalidity of the '395 Patent)

81. Lupin Limited incorporates the allegations set forth in paragraphs 54 through 74 of the Counterclaims as if fully set forth herein.

82. The '395 patent, including claims 1 through 6 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

83. There is an actual case or controversy as to the invalidity of claims 1 through 6 of the '395 patent.

Fourth Count
(Declaration of Noninfringement of the '395 Patent)

84. Lupin Limited incorporates the allegations set forth in paragraphs 54 through 74 of the Counterclaims as if fully set forth herein.

85. Lupin Limited's drospirenone and ethinyl estradiol tablets do not infringe any valid and enforceable claim of the '395 patent.

86. There is an actual case or controversy as to the infringement of claims 1 through 6 of the '395 patent.

PRAYER FOR RELIEF

WHEREFORE, Lupin prays that this Court enter a judgment against Plaintiffs:

A. Declaring that the claims of the ’652 and ’395 patents are invalid;

B. Declaring that Lupin does not infringe the claims of the ’652 and ’395 patents;

C. Awarding Lupin its costs and expenses incurred in this action;

D. Declaring that this case is an exception case under 35 U.S.C. § 285 and awarding Lupin its attorney’s fees, costs, and expenses; and

E. Awarding Lupin any further additional relief as the Court deems just and proper.

Dated: September 27, 2010

/s/ Amin Kassam

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